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Assessing the effectiveness of mouthwashes against SARS-CoV-2 before dental procedures

Submission date
23/06/2021

Recruitment status
No longer recruiting

Registration date
24/06/2021

Overall study status
Completed

Last Edited
18/12/2023

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. Dentistry is currently severely limited during the COVID-19 pandemic. Aerosol-generating dental procedures may spread the virus from asymptomatic COVID-positive patients. The COVID virus has been already shown to be present in saliva in significant quantities. Dental staff are currently protected through the use of appropriate Personal Protective Equipment (PPE), but there are concerns about the safety of the next patient to enter the surgery, as there could theoretically be viable virus circulating in the air from the previous patient's procedure. As a result of this, patients are having difficulty or may be reluctant to access dental appointments and care, leading to a backlog of cases, the potential for oral health in the UK to suffer and many dental practices to become financially unviable or the cost of treatment to increase. This study hopes to address the problem by testing whether the SARS-Cov-2 virus can be made inactive before dental procedures.
A number of dentists have already suggested the idea of using mouthwashes to inactivate the virus, not only for dental procedures, but as part of a broader measure to help control the spread of the pandemic in the population. Pre-procedural mouthwashes have been in common use in dentistry for many years and have proven to reduce bacteria in aerosols although not viruses. An investigation has identified four commercially available mouthwashes in the laboratory setting. This study aims to develop this theory further by asking COVID-positive patients to provide saliva samples at timed intervals to test the effectiveness of various mouthwashes against the SARS-Cov-2 virus, and also the length of time they are effective for. It is important to know if the virus is still infective rather than just knowing its presence, so live culture of samples is necessary. It is not currently known how much virus is required to infect an individual.

Who can participate?
People over the age of 16 years who have had a positive COVID-19 test within the last 72 hours with mild to moderate symptoms of COVID-19

What does the study involve?
The study involves participants providing saliva samples before and after using a mouthwash (Orawise+, Listerine Total Care, Listerine Cool Mint) or a control solution (bottled water). Samples will be taken pre mouthwash, then at 1, 10, 30 and 60 minutes after using a mouthwash.

What are the possible benefits and risks of participating?
There will be no benefit to the participant but the findings may benefit other patients in the future and help provide us with a better understanding of the SARS-Cov-2 virus.

Where is the study run from?
York Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2020 to June 2022

Who is funding the study?
Johnson & Johnson (USA)

Who is the main contact?
Mia Porteous
mia.porteous@york.nhs.uk
Mouthwash@york.nhs.uk

Contact information

Type(s)
Public

Contact name
Miss Mia Porteous

Contact details
York & Scarborough Teaching Hospitals NHS Foundation Trust
York Hospital
Wigginton Road
York
United Kingdom
YO31 8HE
+44 (0)1904 725129
mia.porteous@york.nhs.uk

Type(s)
Scientific

Contact name
Mr David Seymour

Contact details
York & Scarborough Teaching Hospitals NHS Foundation Trust
York Hospital
Wigginton Road

York
United Kingdom
YO31 8HE
+44 (0)1904 725129
David.Seymour@york.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
300106

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 300106, CPMS 49628

Study information

Scientific Title
Investigating the effectiveness of oral antiseptic rinses on SARS-CoV-2 in-vivo - a randomised controlled trial

Study objectives
To test methods of mitigating the risk of SARS-CoV-2 in the dental setting by rendering it non-infective prior to procedures. The methods for investigation will be the use of a pre-procedural mouthwash.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/06/2021, North of Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224 558458; gram.nosres@nhs.scot), REC ref: 21 /NS/0073

Study design
Single-centre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
Participants with a positive COVID test within the last 72 hours will be randomised to four types of mouthwash by a random number generator. The mouthwashes to be tested are as follows:
1. Orawise+ (hypochlorous acid)
2. Listerine Total Care (eucalyptol, thymol, menthol, sodium fluoride, zinc chloride)
3. Listerine Cool Mint (alcohol, eucalyptol, thymol, menthol)
4. Control group (bottled water)

Participants will be randomised to a mouthwash or the control group. Saliva samples will be collected prior to mouth washing (baseline), then at 1, 10, 30 and 60 minutes after mouth washing. These saliva samples will then be frozen and cultured for viable virus with Public Health England.

Intervention Type
Other

Primary outcome measure
Levels of SARS-CoV-2 in saliva samples measured quantitatively by determining the 50% tissue culture infectious dose (TCID50) and the infectious virus titre in TCID50/ml, at baseline (pre-mouth washing) and 1, 10, 30 and 60 minutes after mouth washing

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/07/2020

Completion date
16/06/2022

Eligibility

Key inclusion criteria
1. Participants aged over 16 years with a positive COVID-19 swab test in the last 72 hours
2. Participants will only be recruited if they are well enough, i.e. only showing mild to moderate symptoms/signs of COVID-19 infection

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
92

Total final enrolment
92

Key exclusion criteria
1. Refusal of consent
2. Participants known to be pregnant
3. Participants who have allergies to any of the mouthwashes used in the trial

Date of first enrolment
28/06/2021

Date of final enrolment
16/06/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
York Hospital
Wigginton Road
York
United Kingdom
YO31 8HE

Sponsor information

Organisation
York Teaching Hospital NHS Foundation Trust

Sponsor details
Wigginton Road
York

England
United Kingdom
YO31 8HE
+44 (0)1904 725123
mouthwash@york.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.yorkhospitals.nhs.uk

ROR
https://ror.org/027e4g787

Funder(s)

Funder type
Industry

Funder Name
Johnson and Johnson

Alternative Name(s)
Johnson & Johnson, johnson & Johnson Services, Inc., Johnson&Johnson, , Johnson & Johnson Private Limited, , J&J, JNJ

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. The statistical analysis plan can be made available by contacting the main study contact should this be required.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V9.0	14/06/2021	24/06/2021	No	No
HRA research summary			28/06/2023	No	No
Preprint results		13/10/2023	18/12/2023	No	No